UNITED STATES DEPARTMENT OF COMMERCE
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PD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/123,620	07/28/98	ELFORD H	HEBVR-5

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EXAMINER	
FONDA,K	
ART UNIT	**PAPER NUMBER**
1623	10

DATE MAILED: 12/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Advisory Action

Application No.	Applicant(s)
09/123,620	Elford
Examiner	**Group Art Unit**
Kathleen Kahler Fonda	1623

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *11-18-99* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☒ will not be entered because:

☒ they raise new issues that would require further consideration and/or search. (See note below).

☒ they raise the issue of new matter. (See note below).

☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: *No free radical scavengers or ribonucleotide reductase inhibitors other than the compound of claim 1 are described in the specification. Therefore proposed claims 13 and 14 encompass new matter.*

☐ Applicant's response has overcome the following rejection(s):

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
as stated in the Office action of 9-13-99, a compound which is an inhibitor of a reductase, or a free radical scavenger, must necessarily be an oxidizing agent. With regard to free radicals, note the attached excerpt from Toxicology,

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: *none*

Claims objected to: *none*

Claims rejected: *1-11*

☐ The proposed drawing correction filed on _____ ☐has ☐has not been approved by the Examiner.

☒ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). *8* .

☒ Other ***on PTO Form 892. The Examiner considers the compound of claim 1 to be analogous to glutathione.*

KATHLEEN KAHLER FONDA
PRIMARY EXAMINER
ART UNIT 1623

The specification is objected to as informal because at page 6, line 5, the recitation of "4,252,322" is apparently incorrect. This patent, which the Examiner has considered and listed on the attached PTO Form 892 as reference B, is entitled "Bingo Board With Bonus Games Feature", and appears to have no relevance to the instant invention. The Examiner suggests that the reference be deleted. Applicant is advised that correction of the number will constitute new matter unless support is provided by another portion of the specification as filed.

Claim 1 is objected to as informal because the number zero has been used in place of the letter O in lines 7-8; that is, "or 0-phenyl, R' is 0" should be --or O-phenyl, R' is O--.

Claim 10 is objected to as informal because "arteroisclerosis" should be --arteriosclerosis--. However, Applicant should note the rejection below wherein a disease state is held not to be an "external agency".

Claims 4 and 8 are objected to under 37 CFR 1.75 as being substantial duplicates of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims are duplicative because claims 4

and 8 merely recite inherent properties of the compounds of claim 1. Thus the subject matter covered by claims 4 and 8 does not differ from that covered by claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the specification does not state that the external agency may be "the result of a tissue transplant, an organ transplant or a cell transplant in a mammal", "arteroisclerosis" [sic], or "diabetes". Because claims 9-11 are originally filed claims, this rejection may be overcome by amending the specification to recite the omitted subject matter. However, Applicant's attention is drawn to the indefiniteness rejection of claims 9-11 below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 is indefinite because the phrase "NF-κB inhibiting amount" has no particular art-recognized meaning and has not been adequately defined in the specification as filed.

Claim 1 is also indefinite because the term "and" in lines 8 and 9 would appear to indicate that salts and phenol derivatives must be administered together with a compound having the cited formula. This does not appear to be Applicant's intention.

Claim 2 is indefinite because the phrase "includes, but is not limited to" at lines 2-3 does not provide any limitation to the claim.

Claims 9-11 are indefinite because none of "the result of a tissue transplant, an organ transplant or a cell transplant in a mammal", "arteroisclerosis" [sic], or "diabetes" is seen to be an "external agency" as Applicant employs this phrase in the specification. Transplants are procedures performed on a patient, while arteriosclerosis and diabetes are disease states.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over VAN'T RIET *et al.* (A) in view of Applicant's admission.

Applicant claims a process for inhibiting NF-κB in a mammalian cell by administration of a hydroxybenzoic acid or derivative thereof as set forth in claim 1.

VAN'T RIET teaches compounds coextensive in scope with those of the instant claims, including the specific compounds of claims 5-7; see the Summary of the Invention. Note also the first full paragraph on page 6 of the instant specification. VAN'T RIET also discloses that these compounds are ribonucleotide reductase inhibitors and free radical scavengers; see the Abstract.

Applicant admits that it was known in the art at the time of the invention that anti-oxidants inhibit activation of NF-κB.

See page 2, lines 7-8, which is part of the "Background of the Application" section of Applicant's specification.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to inhibit NF-κB in a mammalian cell by administration of a hydroxybenzoic acid or derivative thereof. Because the compounds are taught by VAN'T RIET to be ribonucleotide inhibitors and free radical scavengers, an ordinarily skilled chemist would immediately recognize them to be anti-oxidants. Applicant had admitted that it was known in the art at the time of the invention that anti-oxidants inhibit activation of NF-κB. Therefore, an ordinarily skilled worker would have been motivated, with a reasonable expectation of success, to inhibit NF-κB in a mammalian cell by administration of a hydroxybenzoic acid or derivative thereof, regardless of the cause of the NF-κB activation.

No claim is allowed.

The following references are cited to indicate the state of the art at the time of the invention more completely: Elford *et al.* (C and E) and van't Riet *et al.* (D, F, A2, and B2).

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of

the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached from Tuesday through Friday, as well as on alternate Mondays, between 7:30 a.m. and 5:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Marian Knode at (703) 308-4311. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda

Kathleen Kahler Fonda, Ph.D.
Primary Examiner
Art Unit 1623